DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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May 11, 2015

BioMedical Enterprises, Incorporated
Mr. Joe W. Soward
Director, Quality, Compliance and Regulatory Affairs
14785 Omicron Drive, Suite 205
San Antonio, Texas 78245

Re: K150125
Trade/Device Name: Elite™ Nitinol Fixation System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: JDR
Dated: April 8, 2015
Received: April 13, 2015

Dear Mr. Soward:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing

(21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150125

Device Name
Elite™ Nitinol Fixation System

Indications for Use *(Describe)*

• Fracture and osteotomy fixation and joint arthrodesis of the hand and foot.
• Fixation of proximal tibial metaphysis osteotomy.
• Fixation of small fragments of bone (i.e. small fragments of bone which are not comminuted to the extent to preclude staple placement). These fragments may be located in long bones such as the femur, fibula and tibia in the lower extremities; the humerus, ulna or radius in the upper extremities; the clavicle and ribs; and in flat bone such as the pelvis, scapula and sternum.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(K) Summary

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807.92, this information serves as a Summary of Safety and Effectiveness for the use of the Elite™ Nitinol Fixation System.

1. Submitted By:

BioMedical Enterprises, Inc.
14785 Omicron Dr., Suite 205
San Antonio, TX 78245

Date: May 4, 2015

Contact Person:

Joe Soward
Director Quality Compliance and Regulatory Affairs
Office: 210-881-0011
Fax: 210-677-0355

2. Proprietary Name: Elite™ Nitinol Fixation System

Common Name: Bone Staple

Classification Name and Reference: Single/multiple component metallic bone fixation appliances and accessories
(21 CFR 888.3030 – Class II)

Device Product Code, Device Panel: JDR – Orthopedic

3. Primary Predicate: Speed Titan™ (formerly cleared as Speed XL K133780)

Reference Devices: OSSplate™ (formerly cleared as Memograph Staple System K993714), Speed Triad™ (K133844)

4. Device Description:

The Elite™ Nitinol Fixation System, like primary predicate Speed Titan™ K133780, is a Nitinol implant for bone fixation and is designed to be delivered to the operating room in an “open” (legs parallel) and constrained state. The Elite™ Nitinol Fixation System was designed for surgeons who desire additional fixation points for increased rotational stability. The implant does not require any external heating. The implant is fully active at room and body temperature so that the legs compress after release from insertion instrument (additional legs in Straight design compress in tandem).

The primary differences between the Elite™ Nitinol Fixation System and the cleared Speed Titan™ K133780 are the configurations featured. The Speed Titan™ K133780 is a staple with two legs, while the Elite™ Nitinol Fixation System introduces three configurations: a Straight (with two and four legs), a Y-shape (three and four legs) and an H-shape (four legs).

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5. Intended Use

The Elite™ Nitinol Fixation System is indicated for fracture and osteotomy fixation and joint arthrodesis of the hand and foot. Fixation of proximal tibial metaphysis osteotomy.
Fixation of small fragments of bone (i.e. small fragments of bone which are not comminuted to the extent to preclude staple placement). These fragments may be located in long bones such as the femur, fibula and tibia in the lower extremities; the humerus, ulna or radius in the upper extremities; the clavicle and ribs; and in flat bone such as the pelvis, scapula and sternum.

6. Technological Characteristics Comparison

The Speed Titan™ K133780 was originally cleared as Speed XL in K133780. It was introduced in two sizes and featured a wide, flat bridge dimension for use in midfoot/hindfoot procedures. The Speed Titan™ K133780 was additionally cleared as part of bundle submission K142292 which expanded its indications for use and size offerings.

The Elite™ Nitinol Fixation System and primary predicate Speed Titan™ K133780 share the same technological characteristics. More specifically, they share the same indications and intended use and are both fabricated from nitinol, following same manufacturing procedures. The only modifications to the device involve changes in geometry related to number of legs, leg width, and implant shapes (Straight, Y-shape and H-shape). The straight shape configurations are similar in shape to the Speed Titan™ K133780. The Y-shape and H-shape configurations are similar in shape to the reference Speed Triad™ K133844 and OSSplate™ K993714, respectively.

7. Substantial Equivalence – Non-Clinical Evidence

Performance testing includes: Corrosion (ASTM F2129-08), Elastic Static Bending (ASTM F564-10, A4) Pull-out Fixation Strength (ASTM F564-10, A2) and MR Compatibility (ASTM F2052, ASTM F2213, ASTM F2119, ASTM F2182) results of which demonstrate substantial equivalence or better.

8. Substantial Equivalence – Clinical Evidence

N/A

9. Substantial Equivalence – Conclusions

The design characteristics of the subject devices do not raise any new types of questions regarding safety or effectiveness. From the evidence submitted in this 510(k), the subject devices can be expected to perform at least as well as the predicate systems and are substantially equivalent. The safety and effectiveness of the Elite™ Nitinol Fixation System is adequately supported by testing, substantial equivalence information, materials information and comparison of design characteristics provided within this premarket submission.

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